

PTO/SB/21 (08-03)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/646,990
	Filing Date	August 21, 2003
	First Named Inventor	Nikhilesh N. SINGH
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	53 pages + 8 refs.	Attorney Docket Number 559142000500

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment/Reply  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Information Disclosure Statement - 3 pages  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copy of Application Serial No. 10/646,659 - 45 pages Form PTO-1449 + duplicate copy - 4 pages Eight (8) references Return receipt postcard
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	MORRISON & FOERSTER LLP Mika Mayer - 47,777	25226
Signature		
Date	November 10, 2003	

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

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(Patricia M. Ellison)



PATENT  
Docket No. 559142000500

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Patricia M. Ellison

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Nikhilesh N. SINGH and Natasha N.  
SINGH

Serial No.: 10/646,990

Filing Date: August 21, 2003

For: COMPOSITIONS FOR DELIVERING  
THERAPEUTIC AGENTS ACROSS  
THE ORAL MUCOSA

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Pursuant to the USPTO notice dated July 11, 2003, waiving the requirement under 37 C.F.R. § 1.98 (a)(2)(i) to provide copies of U.S. Patents and U.S. Published Applications, copies of those references numbered 1 through 28 are not submitted. Copies of foreign patent documents and non-patent literature are submitted herewith in accordance with 37 C.F.R. § 1.98 (a)(2). The Examiner is requested to make these documents of record.

Applicants would like to draw the Examiner's attention to the co-pending application (copy attached) listed below:

Application Serial No.: 10/646,659, N. Singh and N. Singh, filed August 21, 2003.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of \_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

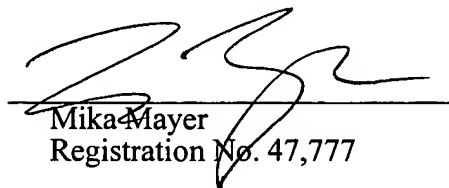
The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 559142000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 10, 2003

Respectfully submitted,

By:



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Form PTO-1449

Docket Number 559142000500

Application Number 10/646,990

# INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Applicant

Nikhilesh N. SINGH and Natasha N. SINGH

Filing Date August 21, 2003

Group Art Unit Not Yet Assigned

Mailing Date November 10, 2003

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	01/17/2002	2002/0006440	Cherukuri			
	2.	02/14/2002	2002/0018800	Pinney et al.			
	3.	04/18/2002	2002/0044960	Cherukuri			
	4.	04/18/2002	2002/0044962	Cherukuri et al.			
	5.	07/25/2002	2002/0098264	Cherukuri et al.			
	6.	08/01/2002	2002/0102304	Pinney et al.			
	7.	10/31/2002	2002/0160043	Coleman			
	8.	12/12/2002	2002/0187188	Cherukuri			
	9.	03/13/2003	2003/0049208	Ream et al.			
	10.	10/02/2003	2003/0185884	Singh et al.			
	11.	04/23/1974	3,806,290	Graff et al.			
	12.	04/24/1979	4,151,270	Ream et al.			
	13.	09/20/1983	4,405,647	Fisher et al.			
	14.	09/05/1989	4,863,737	Stanley et al.			
	15.	07/21/1992	5,132,114	Stanley et al.			
	16.	02/22/1994	5,288,497	Stanley et al.			
	17.	02/22/1994	5,288,498	Stanley et al.			
	18.	07/21/1998	5,783,207	Stanley et al.			
	19.	07/28/1998	5,785,989	Stanley et al.			
	20.	10/20/1998	5,824,334	Stanley et al.			
	21.	01/05/1999	5,855,908	Stanley et al.			
	22.	03/06/2001	6,197,334	Renda			
	23.	07/24/2001	6,264,981	Zhang et al.			
	24.	02/05/2002	6,344,222	Cherukuri et al.			
	25.	03/19/2002	6,358,060	Pinney et al.			
	26.	10/15/2002	6,465,003	Ream et al.			
	27.	04/22/2003	6,552,024	Chen et al.			

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.



Form PTO-1449

Docket Number 559142000500

Application Number 10/646,990

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Applicant

Nikhilesh N. SINGH and Natasha N. SINGH

Filing Date August 21, 2003

Group Art Unit Not Yet Assigned

Mailing Date November 10, 2003

28.	05/06/2003	6,558,692	Ream et al.			
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## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
	29.	03/16/2000	WO 00/13662	WIPO				
	30.	12/27/2002	WO 02/102357	WIPO				
	31.	05/15/2003	WO 03/039518	WIPO				
	32.	10/16/2003	WO 03/084515	WIPO				

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	33.	Green, J.A. et al. (1989). "The Efficacy and Safety of GR38032F In The Prophylaxis of Ifsofamide-Induced Nausea and Vomiting," <i>Cancer Chemother. Pharmacol.</i> 24:137-139.
	34.	Kansy, M. et al. (1998). "Physicochemical High Throughput Screening: Parallel Artificial Membrane Permeation Assay in the Description of Passive Absorption Processes," <i>J. Med. Chem.</i> 41(7):1007-1010.
	35.	Lieberman, H.A. et al. eds. (1989). <u>Pharmaceutical Dosage Forms: Tablets</u> Second Edition Marcel Dekker, Inc.: New York, NY. Vol. 1, pp. vii-x. (Table of Contents Only.)
	36.	Rathbone, M. J. et al. (1994). "The Oral Cavity As A Site For Systemic Drug Delivery," <i>Adv. Drug Del. Rev.</i> 13:1-22.

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DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.